Proposed Registration Decision PRD2016-15

# Dyson Humidifier

*(publié aussi en français)*

**18 May 2016**

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0878 (print)
1925-0886 (online)

Catalogue number: H113-9/2016-15E (print version)
H113-9/2016-15E-PDF (PDF version)

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# Overview

## Proposed Registration Decision for Dyson Humidifier

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Dyson Humidifier, a humidifier which uses ultraviolet C light (UVC) to sanitize the humidifier water to reduce bacterial levels by 99.9%.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Dyson Humidifier.

## What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on Dyson Humidifier, the PMRA will consider any comments received from the public in response to this consultation document.[3] The PMRA will

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

then publish a Registration Decision[4] on Dyson Humidifier, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

## What Is Dyson Humidifier?

Dyson Humidifier is a device which uses an ultraviolet C light to sanitize water in a humidifier before misting. Ultraviolet C light is not currently registered for use in Canada. A bulb in the humidifier emits ultraviolet C light at 254 nm at 5.9-9.5 $w/m^2$ and the ultraviolet C light photons cause direct bacterial DNA damage by inducing the formation of DNA lesions which block DNA replication and RNA transcription which inevitably leads to loss of cell viability.

## Health Considerations

### Can Approved Uses of the Dyson Humidifier Affect Human Health?

**The Dyson Humidifier is unlikely to affect human health when used according to label directions.**

The Dyson Humidifier is an electrically powered residential humidifier that uses ultraviolet C (UVC) light to control the levels of bacteria in the humidifier water. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. Only uses for which the exposure is well below levels that cause no health concerns are considered acceptable for registration.

The skin and the eye are the most important sites of ultraviolet light induced effects following acute exposure. The main acute skin lesion from exposure to ultraviolet radiation is erythema or sunburn. Erythema can be induced by ultraviolet light (including UVC) and the wavelength of light, skin type, and skin pigmentation all influence whether it will occur. Other acute skin responses to ultraviolet light include tanning and photosensitivity. The principal acute effects of UVC on the eye are photokeratitis (inflammation of the cornea) and photoconjunctivitis (inflammation of the conjunctiva).

Registrant-supplied data on the use pattern for the Dyson Humidifier as well as information from the published scientific literature on solar radiation/ultraviolet light was assessed for the potential of UVC to cause chronic adverse effects on the skin and eyes, effects on the immune system, genotoxicity, and cancer. The risk from exposure to UVC from use of the Dyson Humidifier is low, if not negligible, given that the UVC lamp is totally enclosed within the humidifier, the water trough is interlocked by two independent sensors to prevent accidental exposure to lamp emissions, there are precautionary statements on the hazards of UVC on the label and in the

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4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

operating manual, and the device is to be turned off and unplugged during maintenance and clean-ups.

**Risks in Residential and other Non-Occupational Environments**

**Risks to domestic users and bystanders from ultraviolet light are not of concern.**

Risks from UVC light to domestic users of the Dyson Humidifier and bystanders in the locations where the device is to be used are also not expected to be of concern. The UVC lamp is totally enclosed within the humidifier, the water trough is interlocked by two independent sensors to prevent accidental exposure to lamp emissions, there are precautionary statements on the hazards of UVC on the label and in the operating manual, and the device is to be turned off and unplugged during maintenance and clean-ups. Therefore, there will be no dermal or ocular exposure to UVC light during the normal operation, maintenance, and clean-ups of the Dyson Humidifier. Based on a testing report submitted by the applicant, the effective irradiance of the UVC light emitted from the device during operation is less than international limits for controlling photobiological hazards from ultraviolet light sources and thus, does not present a health concern. Although the UVC lamp in the Dyson Humidifier contains gaseous mercury, the mercury is enclosed in the sealed glass tube of the lamp and the lamp is completely enclosed in the device. Consequently humidifier users are not expected to be exposed. In addition, the operating manual provides instructions on contacting the humidifier manufacturer if the UVC lamp needs to be replaced. Similar to other electrical devices that utilize UVC lamps, there is also the potential for the Dyson Humidifier to emit ozone during normal operation. However, the UVC lamp is coated to prevent the emission of wavelengths of light that could generate ozone and registrant-supplied measurements of maximum ozone emissions from the device were well below the Health Canada Residential Indoor Air Quality Guideline for ozone. Consequently, ozone emissions from the Dyson Humidifier are not expected to be of concern to users or bystanders.

## Value Considerations

**What Is the Value of Dyson Humidifier?**

**Dyson Humidifier is a humidifier which uses an ultraviolet C light (UVC) to sanitize the humidifier water to reduce bacterial levels by 99.9% during the start up cycle of the humidifier before misting commences.**

The use of an ultraviolet C light within a humidifier, such as Dyson Humidifier, capable of reducing the bacterial population in the water by 99.9% prior to misting, would reduce the need for general maintenance of the humidifier by continuously controlling the growth of bacteria in the water and preventing the development of biofilm over time on the internal surfaces of the device.

## Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Dyson Humidifier to address the potential risks identified in this assessment are as follows.

**Key Risk-Reduction Measures**

**Human Health**

The label and operating manual for the Dyson Humidifier device includes the following precautionary statements to identify the hazards and minimize human health risks from UVC: "This appliance contains a UVC emitter. Unintended use of the appliance or damage to the housing may result in the escape of UVC radiation. UVC radiation may cause eye and skin irritation. Avoid exposing eyes and skin to UVC radiation." Also, the operating manual contains information on the presence of mercury gas in the UVC lamp used in the Dyson Humidifier and instructions on contacting the humidifier manufacturer if the UVC lamp needs to be replaced.

## Next Steps

Before making a final registration decision on Dyson Humidifier, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

## Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on Dyson Humidifier (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

# Science Evaluation

## Dyson Humidifier

## 1.0 The Active Ingredient, Its Properties and Uses

The Dyson Humidifier device is a humidifier which uses ultraviolet C light (UVC) to sanitize the humidifier water to reduce bacterial levels by 99.9%.

### 1.1 Directions for Use

Controls 99.9% of Bacteria in Humidifier Water

Water passes over a UVC emitter to ensure that it is 99.9% bacteria-free before misting commences. This takes approximately 3 minutes. During this time humidity targets can be set.

### 1.2 Mode of Action

Dyson Humidifier uses ultraviolet light to sanitize the humidifier water prior to misting and being emitted from the device. Ultraviolet radiation has widely recognized antimicrobial efficacy, which depends on three factors: the frequency and strength of the light and the time of exposure. Dyson Humidifier uses a UVC bulb that emits light at 254 nm at 5.9-9.5 $w/m^2$. UVC photons cause direct bacterial DNA damage by inducing the formation of DNA lesions which block DNA replication and RNA transcription.

## 2.0 Impact on Human and Animal Health

### 2.1 Toxicology Summary

The Dyson Humidifier uses UVC at a wavelength of 254 nm to reduce bacterial levels in the humidifier water. Information obtained from the published scientific literature was considered adequate to address the toxicology information requirements for this device.

Ultraviolet radiation has wavelengths ($\lambda$) between 100 and 400 nanometres (nm) in length and is classified as UVA ($\lambda$ = 315–400 nm), UVB ($\lambda$ = 280–315 nm), and UVC ($\lambda$ = 100–280 nm). The relative effectiveness of different ultraviolet radiation wavelengths in producing biological effects on the eye, skin and other tissues is known as an action spectrum.

The skin and the eye are the principal target organs for potential adverse effects following acute exposures to UVC. The main acute lesion to the skin from ultraviolet radiation exposure is erythema which appears 3-5 hours after exposure, reaches a maximum between 8 and 24 hours, and dissipates over a few days. After longer exposures, erythema can progress to pain, edema, blistering, and peeling. Erythema can be induced by ultraviolet A light (UVA), ultraviolet B light (UVB), and ultraviolet C light (UVC), with the wavelength of light, skin type, and pigmentation all influencing whether erythema will be produced. UVC in the 250–290 nm spectral region is most effective for minimal erythema with decreasing effectiveness as wavelengths increase. Skin

tanning and thickening are additional acute responses to ultraviolet light exposure along with photosensitization, a toxic reaction from reactive chemical species formed when doses of ultraviolet radiation less than those that induce erythema interact with certain chemicals that an individual has been exposed to via the skin or other routes. Photosensitized individuals may develop rashes, sunburns or other effects after exposure to light of durations and intensities that would normally not affect them. The action spectrum for most photosensitizers is 280–430 nm. Photosensitizers include phototoxins that can induce effects localized to the skin (i.e. skin irritation) and photoallergens that can trigger a systemic immune response beyond the site of skin exposure to ultraviolet radiation.

The principal acute effects of ultraviolet light on the eye are photokeratitis (inflammation of the cornea) and photoconjunctivitis (inflammation of the conjunctiva), also known as "snow blindness" and "welders flash". Symptoms gradually increase from itchiness, to increased tearing, to severe pain, and photophobia. Both conditions are usually reversible after 24 to 48 hours and are similar to sunburn of the skin. Light in the UVC spectrum is capable of inducing photokeratitis and photoconjunctivitis. In a number of published case studies, accidental high radiant exposures to UVC from germicidal lamps and electronic fly killers have resulted in phoconjunctivitis that was present a few hours after exposure and persisted for as long as 30 days in some subjects. Skin effects (i.e. erythema, irritation) were also reported in these case studies. In animal studies ultraviolet radiation has induced acute cataracts and retinal damage but at wavelengths greater than the UVC spectrum.

Chronic solar ultraviolet radiation exposure can induce clinical and histological changes in the skin known as photoageing. The skin appears dry with deep wrinkles, atrophy, accentuated skin furrows, sagging, loss of elasticity, mottled pigmentation, highly visible superficial blood vessels, age spots, yellow papules and plaques, diffuse erythema, and subcutaneous blood spots. Based on a mouse model of photoageing, effects were attributed more to the UVB spectrum in solar ultraviolet radiation.

Effects of chronic ultraviolet radiation (mainly UVA and UVB) exposure on the eye include pterygium ("surfers eye"), a benign growth of the nasal side of the conjunctiva that encroaches on the cornea; climatic droplet keratopathy (droplet keratitis), a spheroid degeneration of the cornea (i.e. focal deposition of lipids) affecting transparency and leading to blindness in some older populations; and pingueculum, a fibro-fatty degeneration (i.e. non-malignant connective tissue tumour) in the conjunctiva. Chronic ultraviolet radiation (mainly UVB) exposure is also believed to be one of the causative factors in the development of cataracts, optical opacities in the lens of the eye.

Studies in rodents and humans indicate that ultraviolet radiation exposure can suppress immune responses including the suppression of hypersensitivity reactions. In mice, ultraviolet radiation exposure may allow the progression of tumours and the suppression of resistance to skin and systemic microbial infections. In humans associations have been demonstrated between solar ultraviolet radiation exposure and a relapse with increased severity of Herpes Simplex Virus infections and the conversion of benign Herpes Papillomas Virus papillomas to squamous cell carcinoma.

UVA, UVB, and UVC are mutagenic in prokaryotes and mammalian and human cells in vitro. UVA and UVC can also induce chromosomal aberrations in mammalian cells, and UVC can cause aberrations in human cells in vitro. All three types of ultraviolet radiation have induced DNA damage and sister chromatid exchange (SCE) in mammalian cells and human cells in vitro, UVB and UVC have caused DNA damage in irradiated human skin cells in vivo, and UVC has induced SCE in human cells in vitro.

Based on the results of epidemiological studies, solar ultraviolet radiation exposure is a major causal factor for the three most common forms of skin cancer, basal cell carcinoma, squamous cell carcinoma, and malignant melanoma. UVB and UVA are implicated for squamous cell carcinoma along with lifetime cumulative exposure and poor tanning response, but the wavelengths and exposure patterns associated with the other two forms of skin cancer have not been determined. The International Agency for Research on Cancer (IARC) reviewed several studies conducted with mice and rats exposed to UVC from low pressure mercury discharge germicidal lamps that emitted mainly 254 nm light. Tumours were induced in all of the studies. Although a contribution from the UVB spectrum could not be ruled out, it is unlikely that tumour induction was due to UVB alone. IARC also concluded that there is *sufficient evidence* for the carcinogenicity of UVA, UVB, and UVC in experimental animals. UVA, UVB, and UVC were classified as "*probably carcinogenic to humans* (Group 2A).

The mechanisms behind the effects of ultraviolet light on tissues generally involve the absorption of specific wavelengths of light by cellular chromophores such as DNA, RNA, proteins, and other molecules resulting in the production of reactive species or free radicals. The main cellular target for ultraviolet radiation is DNA which has an absorption peak in the UVC spectrum at 260 nm followed by decreasing absorption through the UVB spectrum and no absorption at wavelengths greater than 325 nm. Solar UVB induced DNA damage is believed to be a critical component of the ultraviolet radiation induced carcinogenic pathway. The highest frequency DNA lesions caused by UVC and UVB are cyclobutane type pyrimidine dimers. The P53 gene facilitates the repair of ultraviolet radiation induced DNA lesions. "Signature mutations" in this gene can produce unregulated mitosis and skin cancer. DNA dimers can induce melanogenesis and ultraviolet radiation induced DNA damage/repair can cause cell divisions and skin thickening which are characteristic of tanning.

**Incident Reports**

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Information on the reporting of incidents can be found on the Health Canada website. Since no humidifier devices that use UVC to reduce bacterial levels in water have been registered in Canada, there are no incident reports.

Since the registration of Dyson Humidifier which uses ultraviolet C light to control microbes in humidifier water is a new registration in Canada, there are no incident reports.

## 2.2 Domestic User and Bystander Exposure and Risk Assessment

### 2.2.1 Use Description

The Dyson Humidifier is an electrically powered residential humidifier that uses a UVC emitter (low pressure mercury gas discharge cold cathode lamp) which emits light at a wavelength of 254 nm to reduce bacterial levels in the humidifier water. When the humidifier is initially turned on, the UVC lamp is switched on for 3 minutes to treat water in the trough in the device prior to misting water into the air. A humidity sensor automatically switches the Dyson Humidifier on and off several times during any 24 hour period, but whenever the device is on, the UVC lamp is also on.

### 2.2.2 Domestic User and Bystander Exposure and Risks

The UVC lamp is totally enclosed within the device and the water trough is interlocked by two independent sensors to prevent accidental exposure to the lamp emissions during normal operation.

The operating manual for the Dyson Humidifier specifically indicates that before cleaning, the device should be turned off and unplugged. Specific instructions are provided on the types of solutions that should and should not be used to clean the device, how to clean the device, and the recommended frequency of cleaning. The UVC lamp cover is interlocked to prevent accidental exposure to UVC light during lamp maintenance/replacement. Also, the Dyson Humidifier operating manual provides instructions on contacting the device manufacturer if the UVC lamp needs replacement.

Based on a testing report submitted by the applicant, ultraviolet light emissions from the Dyson Humidifier are in compliance with the International Electrotechnical Commission's (IEC) standard IEC/EN-62471. A Canadian version of this standard, CAN/CSA-C22.2 No. 62471 was adopted in 2012. IEC/EN-62471 provides exposure limits, measurement techniques and a classification scheme for evaluating and controlling photobiological hazards from electrically powered incoherent broadband sources of optical radiation in the 200 to 3000 nm range of wavelengths. Finally, both the label and the operating manual for the Dyson Humidifier include precautionary statements on the potential eye and skin irritation hazards from exposure to UVC.

Because of the safety features of the device, the instructions for normal operation and cleaning/maintenance, the compliance of the device with an appropriate international standard for ultraviolet light emissions, and the precautionary statements on the label and in the operating manual, there are not expected to be any accidental exposures to or risks from UVC light during the normal operation and cleaning/maintenance of the device.

The UVC lamp in the Dyson Humidifier contains mercury in a gaseous form. As noted previously, the UVC lamp is enclosed in the device. Also, the mercury is enclosed in the sealed glass tube of the lamp, and the operating manual contains a precautionary statement on the presence of low levels of mercury in the device and instructions on contacting the company if the UVC lamp needs to be replaced. Therefore, no exposures or risks from mercury are expected during the normal operation and cleaning/maintenance of the device.

Wavelengths of light less than 185 nm are capable of inducing the formation of ozone. The manufacturer of the UVC lamp indicated that the lamp has been treated to prevent the emission of light at wavelengths less than 185 nm and based on applicant supplied test results, maximum ozone emissions from the Dyson Humidifier are two to four times less than Health Canada's residential indoor air quality guideline for ozone. As a result, exposures to and risks from airborne ozone during the normal operation of the device, are not expected to be of concern.

As outlined previously, the UVC lamp is totally enclosed in the Dyson Humidifier, both the water trough and the UVC lamp cover are interlocked with sensors, the device is to be switched off and unplugged during cleaning/maintenance, and the device is in compliance with an appropriate international standard for UVC light emissions. Consequently, bystanders are not expected to be exposed to or experience any risks from UVC light during the normal operation, clean-up, and maintenance of the Dyson Humidifier.

## 3.0 Value

### 3.1 Consideration of Benefits

It is widely recognized that humidifiers are able to reduce the water to a fine spray, and therefore have the potential to aerosolize water-borne microorganisms if they are present in the water tank. Dyson Humidifier reduces this risk by using a UVC light and a controlled water flow path from the water tank, to reduce bacterial levels in the water. The bulb is replaceable and therefore can easily be changed to prolong the life of the unit.

As UV disrupts the DNA of the bacteria, there is very little published evidence that resistance can evolve over time. UVC cause direct DNA damage by inducing the formation of DNA lesions (photoproducts), most notably pyrimidine dimers, which block DNA replication and RNA transcription. The UVC in the Dyson Humidifier device provides a sufficiently high dosage to ensure that nucleic acid is damaged beyond repair.

### 3.2 Effectiveness Against Pests

Five separate lots of the Dyson Humidifier device were tested against each of four different organisms for a total of twenty separate trial runs. All trials demonstrated that Dyson Humidifier is able to reduce microbial levels in the humidifier water by $\geq$99% within the three minute start up cycle before misting commences.

### 3.3 Non-Safety Adverse Effects

No non-safety adverse effects have been identified or reported from the use of this product.

## 4.0 Pest Control Product Policy Considerations

### 4.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the

environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e. persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, UVC was assessed in accordance with the PMRA Regulatory Directive DIR99-03[5] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- UVC does not meet all Track 1 criteria, and is not considered a Track 1 substance.
- UVC is not a chemical product and therefore, it does not contain any impurities and is not expected to form any transformation products that meet all Track 1 criteria.

### 4.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6]. The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03,[8] and DIR2006-02;[9] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

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[5] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

[6] *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

[7] NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

[8] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

[9] DIR2006-02, *Formulants Policy and Implementation Guidance Document.*

- UVC is not a chemical product and therefore it does not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.
- The Dyson Humidifier is an UVC device that does not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.
- The use of formulants in registered pest control products is assessed on an ongoing basis through the PMRA formulant initiatives and Regulatory Directive DIR2006-02.

## 5.0 Summary

### 5.1 Human Health and Safety

The database of health effects information from the published scientific literature is adequate to characterize the majority of health effects from exposure to UVC light. Acute exposures to UVC can cause erythema (sunburn) of the skin, photokeratitis (inflammation of the cornea), and photoconjunctivitis (inflammation of the conjunctiva). Other potential effects of acute solar ultraviolet radiation exposure include tanning and photosensitization in susceptible individuals. Chronic effects of ultraviolet light exposure have been mainly associated with solar radiation (i.e. not specifically UVC) and include photoageing of the skin, and benign growths and degenerations of the cornea and conjunctiva of the eye. Solar ultraviolet light can also suppress immune responses. Finally, UVC light has been demonstrated to be genotoxic and has been classified as probably carcinogenic to humans by IARC.

Based on the design of the Dyson Humidifier, the UVC lamp is totally enclosed and there are interlocked sensors to prevent UVC light exposure during normal operation, maintenance and cleanups. Also, there are precautionary statements on the label and in the operating manual on the hazards of UVC light, and UVC emissions from the device comply with an appropriate international standard for controlling photobiological hazards. Normal use, cleaning, and maintenance of the Dyson Humidifier are not expected to result in any unacceptable exposures or risks from UVC light when the device is used according to label directions.

### 5.2 Value

Dyson Humidifier is a humidifier which uses an ultraviolet C light (UVC) to sanitize the humidifier water to reduce bacterial levels by 99.9% during the three minute start up cycle of the humidifier before misting commences. The use of an ultraviolet C light within Dyson Humidifier, which reduces bacterial levels in the water by 99.9% prior to misting, would reduce the need for general maintenance of the humidifier by continuously controlling the growth of bacteria in the water and preventing the development of biofilm over time on the internal surfaces of the device.

## 6.0 Proposed Regulatory Decision

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Dyson Humidifier, a humidifier which uses ultraviolet C light (UVC) to sanitize the humidifier water to reduce bacterial levels by 99.9% during the three minutes start up cycle of the humidifier before

misting commences.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

**Human Health**

The label and operating manual for the Dyson Humidifier device includes the following precautionary statements to identify the hazards and minimize human health risks from UVC: "This appliance contains a UVC emitter. Unintended use of the appliance or damage to the housing may result in the escape of UVC radiation. UVC radiation may cause eye and skin irritation. Avoid exposing eyes and skin to UVC radiation." Also, the operating manual contains information on the presence of mercury gas in the UVC lamp used in the Dyson Humidifier and instructions on contacting the humidifier manufacturer if the UVC lamp needs to be replaced.

## List of Abbreviations

| | |
|---|---|
| DNA | deoxyribonucleic acid |
| IARC | International Agency for Research on Cancer |
| IEC | International Electrotechnical Commission |
| mg | milligram(s) |
| nm | nanometres |
| PCPA | *Pest Control Product Act* |
| PMRA | Pest Management Regulatory Agency |
| ppm | parts per million |
| RNA | ribonucleic acid |
| SCE | sister chromatid exchange |
| TSMP | Toxic Substances Management Policy |
| UVA | ultraviolet A light ($\lambda$ = 315–400 nm) |
| UVB | ultraviolet B light ($\lambda$ = 280–315 nm) |
| UVC | ultraviolet C light ($\lambda$ = 100–280 nm) |
| w/m2 | Watts per square metre; a measure of irradiance |
| $\lambda$ | wavelength |

# References

## A. List of Studies/Information Submitted by Registrant

### 1.0 Human and Animal Health

| PMRA Document Number | Reference |
|---|---|
| 2452514 | 2014, Use Description/Scenario Application and Post-Application, DACO: 5.2 |
| 2491436 | 2015, Mode of Action, DACO: 10.2.1 |
| 2556041 | 2015, Intertek Test Reports per EN62471, DACO: 5.2 |

### 2.0 Value

| PMRA Document Number | Reference |
|---|---|
| 2452515 | 2014, Analysis Certificate, DACO: 10.2.3.2 |
| 2452517 | 2014, Letter Certifying Electrical Safety, DACO: 10.6 |
| 2491436 | 2015, Mode of Action, DACO: 10.2.1 |
| 2491437 | 2015, Description of the Pest Problem, DACO: 10.2.2 |
| 2491439 | 2015, Efficacy: Laboratory Trials, DACO: 10.2.3.2 |
| 2491440 | 2015, Non Safety Adverse Effects, DACO: 10.3.2 |
| 2491441 | 2015, Social and Economic Impact, DACO: 10.4 |
| 2491442 | 2015, Survey of Alternatives, DACO: 10.5.1 |
| 2491443 | 2015, Resistance Management, DACO: 10.5.3 |

## B. Additional Information Considered

### i) Published Information

### 1.0 Human and Animal Health

| PMRA Document Number | Reference |
|---|---|
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